

**Translation**

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**PATENT COOPERATION TREATY**

**PCT**

PCT/FR2003/003922



**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>POLYPEPS F'</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/FR2003/003922</b>	International filing date (day/month/year) <b>29 décembre 2003 (29.12.2003)</b>	Priority date (day/month/year) <b>07 janvier 2003 (07.01.2003)</b>
International Patent Classification (IPC) or national classification and IPC <b>C07K 14/18, C12N 15/51, 15/63, C07K 16/10, G01N 33/576, A61K 48/00, 39/29, A61P 31/14, C12Q 1/70</b>		
Applicant <b>BIOMERIEUX</b>		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand <b>14 juillet 2004 (14.07.2004)</b>	Date of completion of this report <b>11 April 2005 (11.04.2005)</b>
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

FR2003/003922

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_ 1-64 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_ 1-24 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages \_\_\_\_\_ 1/3-3/3 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages \_\_\_\_\_ 1-152 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1, 2, 4, 7, 9, 11, 13 and 3, 5, 6, 8, 10, 12, 16-24 (partially)

because:

☐ the said international application, or the said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1, 2, 4, 7, 9, 11, 13 and 3, 5, 6, 8, 10, 12, 16-24 (partially)

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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International application No.

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## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

The scope of the claims (see below) encompasses a very large number of alternatives of which only a small number are supported by the description. Moreover, the claims include so many variables that the scope of the claims has not been clearly defined. Consequently, said claims fail to comply with the requirements of PCT Article 5 and PCT Article 6.

These defects are such that it is impossible to formulate an opinion on the novelty, inventive step and industrial applicability of claims 1, 2, 4, 7, 9, 11 and 13 as well as 3, 5, 6, 8, 10, 12 and 16 to 24 (in part).

For this reason, an opinion will be given only for the claims that relate to SEQ ID NO 2, SEQ ID NO 152, SEQ ID NO 177, SEQ ID NO 234, SEQ ID NO 281, SEQ ID NO 355, and any subject matter following directly therefrom.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	3, 5, 6, 8, 10, 12, 16-24 (in part)	YES
	Claims		NO
Inventive step (IS)	Claims	3, 5, 6, 8, 10, 12, 16-24 (in part)	YES
	Claims		NO
Industrial applicability (IA)	Claims	3, 5, 6, 8, 10, 12, 16-24 (in part)	YES
	Claims		NO

## 2. Citations and explanations

Reference is made to the following documents:

D1: WO 99/63941 A (BRANCH ANDREA D; STUMP DECHARD D (US); WALEWSKI JOSE L (US)) 16 December 1999 (1999-12-16)

D2: XU Z. ET AL.: "synthesis of a novel hepatitis C virus protein by ribosomal frameshift" EMBO JOURNAL, vol. 20, no. 14, April 2001 (2001-04), pages 3840-3848, XP002246932

D1 describes hepatitis C virus proteins from a +1 or +2 reading frame shift (abstract) as well as portions of said protein that are 40 to 90 % identical over a length of 10 to more than 100 amino acids (page 10, line 20 to page 21, line 10). Said proteins can be expressed in host cells. Antibodies that specifically recognise said proteins are also described (page 14 to page 25).

D2 describes hepatitis C virus protein F (abstract) as well as the detection of antibodies that recognise said protein (figure 7, page 3847, "enzymatic immunoassay").

1. No prior art document describes or suggests the specific antigens and peptides as defined by sequences SEQ ID NO 2, SEQ ID NO 152, SEQ ID NO 177, SEQ ID NO 234, SEQ ID NO 281 and SEQ ID NO 355, which are capable of inducing an immune response by producing IL 10 and optionally gamma IFN. It follows that claims 3, 5, 6, 8, 10, 12 and 16 to 24 (in part) comply with the requirements of PCT Article 33(2) and (3).

2. Claims 3, 5, 6, 8, 10, 12 and 16 to 24 (in part) fail to comply with the requirements of PCT Article 5.

An immune response induced by IL 10 production has been demonstrated only for the epitopes defined in figures 1 to 3 and the polypeptides from HCV of genotypes 1b and 3, i.e. SEQ ID NO 2, SEQ ID NO 152, SEQ ID NO 177, SEQ ID NO 234, SEQ ID NO 281 and SEQ ID NO 355.